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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,486	07/29/2002	Marco Turini	112701335	6915

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,486	TURINI ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-24 and 26-40* is/are pending in the application.

4a) Of the above claim(s) *2,16-22 and 35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-11,13-15,23,24 and 26-34* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-4, 6-11, 13-24 and 26-40are pending in this application.

Applicants argue in their 6/21/2004 remarks that the withdrawn claims 26-34 should be examined. Said claims will be examined.

Applicant is advised that several new references have been found, which necessitate the indication of allowability of some of the claims from the previous Office action to be rescinded. The multiple key features in this invention have been difficult to search due to a lack of consistent searchable terminology and lack of explicit recognition of the features in the prior publications.

Claims 2, 16-22 and 35-40 stand withdrawn as being directed to non-elected subject matter. Claims 1, 3-4, 6-11, 13-15, 23-24 and 26-34 will presently be examined.

Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 28 depends on claim 3. Claim 3 is a "method of producing a composition." Claim 28, however, is a method of administering enterally. At the present time, the language of claim 28, "method of claim 3, wherein the composition is administered enterally" fails to properly depend from claim 3 because the dependence is not well defined. The "method of claim 3" is actually the method of producing a composition, so

a "wherein" clause thereafter should not lead to a different method such as therapy in the absence of further clarifying language.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by DeMichele et al. (US 5,223,285).

DeMichele et al. explicitly disclose a lipid "Blend D" that has the following features (see from column 11, line 40 to column 12, line 28):

43 wt% canola oil + 40 wt% MCT + 13 wt% corn oil + 4 wt% soy lecithin;

n-6/n-3 fatty ratio of 4.50;

Saturated fatty acid excluding MCT = 45.44 - (25.6 + 14.2) = 5.64 wt%;

Presence of α-linolenic acid and other n-3 fatty acids;

Presence of linoleic (n-6 fatty acid); and

Total calories from polyunsaturated fats and saturated fats = 12.78 + 25.08

= 37.86%.

The feature of claim 8, "for enteral administration" is noted, but the lipid Blend D is capable of being delivered via the enteric route since it is a nutritious supplement in the form of a liquid. Moreover, DeMichele et al. clearly disclose that Blend D (commercially known as NUTRIVENT^{TM}) is suitable for enteral administration (column 4, lines 26-27). The claims are thereby anticipated.

Claims 4, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Trimbo et al. (US 5,166,189).

Trimbo et al. explicitly disclose an enteral diet for patients with pulmonary diseases that has 40-55% of total calories from lipids (claim 1, part c), up to 70% of the total triglycerides from MCT's, including an example of 70% (see Table A on column 3; claim 3), and use of long chain triglycerides such as soy oil (claims 1 and 4; Table A on column 3). It is noted that in the example of Table A, only soybean oil is present as the long chain triglyceride source.

n-6/n-3 ratio

Although Trimbo et al. do not expressly state in verbatim language what the n-6/n-3 ratio is in their invention, such ratio can be easily calculated. In the example

shown in Table A, soybean oil lecithin is the only long chain triglyceride source. Content of soybean oil is well documented and would have been immediately available. For example, U.S. Patent no. 5,015,419 (issued on 5/14/1991) shows that soybean oil contains 54.7% n-6 fatty acids (54.5 linoleic + 0.2 eicosenoic) and 8.3% n-3 fatty acid (linolenic). See the table bridging columns 2 and 3. This is n-6/n-3 = 6.6. Trimbo's ratio is therefore clearly within that of the claimed ratio, and Trimbo's composition clearly contains the n-6 and n-3 fatty acids specified in the claims.

Less than about 15% by weight saturated fatty acids excluding MCT

Again, soybean oil fatty acid content would have been immediately available. U.S. Patent no. 5,015,419 (issued on 5/14/1991) shows that soybean oil containsthe saturated fatty acids myristic acid, palmitic acid, stearic acid and arachidic acid at a combined total of 14% of soybean (table bridging columns 2 and 3). Since Trimbo's composition encompasses, for example, 45.8% fats, wherein the soybean oil source is 30% of that amount, it can be readily seen that such an amount of a soybean oil source would provide to the total composition less than about 15 wt% of saturated fatty acids, excluding MCT's.

The claims are thereby anticipated. See MPEP 2131.01 for propriety of referring to another reference to show an inherent characteristic in a 102 ground of rejection.

Claims 3, 26-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trimbo et al. (US 5,166,189).

The discussion set forth above regarding Trimbo's enteral composition is incorporated herein by reference to avoid repetition. Trimbo et al. also disclose "using the appropriate mixing technology" to produce a 1-liter unit, wherein water is added to give the final volume (column 3, lines 5-9).

Applicant's claim language recites "blending the constituents," "liquefying a blended mixture and homogenising the liquefied blended mixture." It is the Examiner's position that Trimbo's disclosure encompasses such steps. Trimbo's water-added, liquid composition is for enteral administration. Blending, liquefying and homogenizing would have to be present in any "appropriate mixing technology" that combines the multiple number of ingredients shown in Trimbo's Table A for ultimate enteral delivery. The claims are thereby anticipated.

In the alternative, at the time the invention was made, such blending, liquefying and homogenizing steps would have been obvious to the ordinary skilled artisan in this field, who would have been motivated to arrive at such steps due to the advantages of a well mixed and homogeneous composition for enteral delivery.

Therefore, the claims 3 and 26-28 are anticipated or at least rendered obvious by the teachings of Trimbo et al.

Claims 1, 3-4, 6-11, 13-14, 23-24, 26-27, 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Pscherer et al. (US 6,008,248).

Pscherer et al. explicitly disclose a Preparative Example 2 (Table 2 on columns 5-6) that contains the following ingredients:

I.	MCT	500g
	soybean oil	400g
	fish oil	100g
	phospholipids	90g
	tocopherol	1g
	sodium oleate	3g
II.	glycerol	250g
	water	to 10 l

Pscherer et al. disclose the fatty acid content of soybean oil and fish oil (Table 1 on columns 5-6), wherein linoleic acid (18:2 n-6), linolenic (18:3 n-3) are present in soybean oil and fish oil, and various other fatty acids such as DHA (22:6 n-3) are additionally present in fish oil. Mixture I containing the MCT, vegetable oil, fish oil and phospholipid are dispersed, mixed with aqueous mixture of glycerol and water with stirring; pH adjusted with sodium oleate, and homogenized in a high pressure homogenizer and then sterilized (column 6, lines 27-35). Pscherer's preparations are used to treat patients in post-operative and post-traumatic conditions or inflammatory

diseases and patients in severe or persistent post-aggression metabolism following operations such as inflammatory diseases, sepsis, shock (column 5, lines 8-26).

n-6/n-3 ratio

Although Pscherer et al. do not expressly state in verbatim language what the n-6/n-3 ratio is in their Preparative Example 2, such ratio can be easily calculated. The fatty acid contents of soybean oil and fish oil are disclosed in Pscherer's Table 1. Simple calculation for 400g soybean oil + 100g fish oil fatty acid content would reveal the fact that Pscherer's Preparative Example 2 has a n-6/n-3 ratio of 2.87[1].

Lipids provide greater than 35% of the total energy of the composition

Combined weight of MCT + soybean oil + fish oil + sodium oleate is 1,003 g, compared to the remaining 341g of other ingredients. Clearly, with such high percentage of caloric lipids in presence, greater than 35% of total energy would have been obtained from lipid sources.

25-70% MCT based on total lipids

500g of MCT is present in admixture with about another 500g of other lipids. This feature is clearly met.

[1] 400g soybean oil contains 55% n-6 and 8% n-3. 100g fish oil contains 4% n-6 and 46% n-3. This comes out to n-6/n-3 = 2.87.

Less than about 15% by weight saturated fatty acids excluding MCT

The fact that Pscherer's composition is clearly within this feature is shown by the fatty acid content in Table 1 (columns 5-6). Simple calculation for Pscherer's Preparative Example 2 shows much less than 15 wt% of saturated fatty acids excluding MCT.

Composition per se: for enteral administration & form such as medicament or nutritive product

Even though Pscherer's composition is not expressly stated as being for enteral administration, there is nothing about the composition that would make it not suitable for such route of administration. The liquefied, homogenized and sterilized lipid formulation for parenteral administration taught by Pscherer et al. would also be suitable for enteral administration as well. Such a formulation is by necessity a medicament or nutritive product.

Method: treating sepsis, treating inflammatory shock

Pscherer's preparations are used to treat patients in post-operative and post-traumatic conditions or inflammatory diseases and patients in severe or persistent post-aggression metabolism following operations such as inflammatory diseases, sepsis, shock (column 5, lines 8-26). Treating sepsis and inflammatory shock is therefore clearly disclosed.

The claims are thereby anticipated.

Claims 1, 10, 13-15, 29, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (US 6,080,787).

Carlson teaches administering a combination of n-6 andn-3 fatty acids at a weight ratio of about 2:1 to 4:1 to treat NEC (necrotizing enterocolitis), which is a life threatening disease characterized by ischemic necrosis and pneumatosis intestinalis, shock, wherein death is common (column 2, lines 31-44; column 3, lines 45-62; claims 1-33). n-6 fatty acid can be arachidonic acid and n-3 fatty acid can be docashexaenoic acid (paragraph bridging columns 3 and 4). Enteral composition is disclosed (column 7, lines 21-37). 100 wt% fatty acid bolus is disclosed, as well as diluted nutritionally complete formulas (column 7, lines 29-37).

While Carlson et al. do not explicitly disclose sepsis treatment, enterally or otherwise, one having ordinary skill in the art would have been motivated to do so with Carlson's formulation because a patient suffering from NEC experiences a variety of diverse life threatening manifestations, of which sepsis would be expected. Therefore, treating NEC would be expected to also treat the various concomitant conditions or manifestations which accompany NEC.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

It is noted for the record that the Examiner and Mr. Robert Barrett discussed on 9/9/2004 amending the claims to cancel claims 3-4 and their dependents and amending claims 1 and 10 to incorporate all of the composition features of claim 10. No agreement was reached.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

JOHN PAK
PRIMARY EXAMINER